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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/620,256 | 07/15/2003 | Orla M. Conneely | HO-P02682US1 | 9752 |
| 26271 | 7590 | 10/18/2005 | EXAMINER | |
| FULBRIGHT & JAWORSKI, LLP 1301 MCKINNEY SUITE 5100 HOUSTON, TX 77010-3095 | | | ROBINSON, HOPE A | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1656 | | |

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/620,256 | CONNEELY ET AL. | |
| | Examiner | Art Unit | |
| | Hope A. Robinson | 1656 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 July 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 24 and 65-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 24 and 65-77 is/are rejected.
- 7) Claim(s) _____ is/are objected to. •
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 15 July 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>10/30/03; 6/6/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Application Status

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

2. Applicant's election without traverse of Group I (claim 24) on July 29, 2005 is acknowledged.

Claim Disposition

3. Claims 1-23 and 25-64 have been canceled. Claims 65-77 have been added. Claim 24 has been amended. Claims 24 and 65-77 are pending and are under examination.

Information Disclosure Statement

4. The Information Disclosure Statements filed on October 30, 2003 and June 6, 2005 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

Specification

5. The specification is objected to because of the following informalities:
 - (a) The specification is objected to because trademarks are disclosed throughout the instant specification and not all of them are capitalized or accompanied by the generic terminology. The use of the trademarks such as TRITON®, for example, have been noted in this application (see page 25). It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.
 - (b) The specification is objected to because on page 1 the continuation data needs to be updated as the present application is a divisional of 09/633,739, which is now U.S. Patent No. 6,635,447.
 - (c) On page 11 and throughout the specification the sequence notation is improper, see for example, "SEQ ID No.1" which should be "SEQ ID NO:1". See also "SEQ. ID. NO.11" on page 30 for example, where there is extraneous periods.

Correction is required.

Abstract

6. The abstract of the disclosure is objected to because it has two paragraphs. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

See MPEP § 608.01(b).

Correction is required.

Drawing

7. The drawings filed on July 15, 2003 are objected to because Figures 6-12 and 16 are dark, thus difficult to ascertain the images represented in the figures. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and

where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 24 and 65-77 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to a process for producing human lactoferrin which comprises culturing a transformant eukaryotic cell containing a recombinant

plasmid, said plasmid comprising a plasmic vector having a polydeoxyribonucleotide which codes for a human lactoferrin protein in a suitable nutrient medium until the human lactoferrin protein is formed and isolating the human lactoferrin protein, however, the claimed nucleic acid is only defined by function (i.e., encoding a protein) not by a structure. Thus, there is no indication of which nucleic acid encodes the protein. Thus the claims lack adequate written description to demonstrate to a skilled artisan that applicant was in possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. See *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Therefore, a biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. For example, even though a genetic code table would correlate a known amino acid sequence with a genus of coding nucleic acids, the same table cannot predict the native, naturally occurring nucleic acid sequence of a naturally occurring mRNA or its corresponding cDNA. See MPEP 2163.

Further, *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the

invention. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of encoded proteins, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993). See MPEP 2163.

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Basis For NonStatutory Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 24 and 65 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent Application number 6,635,447. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant application claim is directed to a process for producing human lactoferrin which comprises culturing a transformant eukaryotic cell containing a recombinant plasmid, said plasmid comprising a plasmic vector having a polydeoxyribonucleotide which codes for a human lactoferrin protein in a suitable nutrient medium until the human lactoferrin protein is formed and isolating the human lactoferrin protein. The claims in the instant application are also directed to eukaryotic cells that are mammalian. The patented claims are directed to a process for producing lactoferrin which comprises culturing a transformant eukaryotic cell containing a recombinant plasmid, said plasmid comprising a plasmic vector having a polydeoxyribonucleotide which codes for a lactoferrin protein in a suitable nutrient medium until the lactoferrin protein is formed and isolating the lactoferrin protein. The two sets of claims differ as the patented claim 1 does not recite "human lactoferrin", however, dependent claim 2 of the patent recites that the cDNA used codes for human, bovine or porcine lactoferrin. Therefore, the two sets of claims are obvious variations of each other as the patented claims are a genus over the instant claims.

Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions as the claim language has the same material. One of ordinary skill in the art would be motivated to modify the instant claims to recite, for example the species human in the instant claim 24 that is contained in the genus as disclosed in claims 1-2 of the patent because it clarifies the claim by providing the specific species. Thus, the instant claims are an obvious variation of the patented claims, therefore *prima facie* obvious.

This is an obvious-type double patenting rejection.

11. Claims 24, 67 and 71-77 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14 and 17 of U.S. Patent No. 6,100,054. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application is directed to a process for producing human lactoferrin, which comprises culturing a transformant eukaryotic cell (i.e. fungal cell such as *Aspergillus* (i.e. *oryzae*, *niger*, *nidulans* and *awamori*) containing a recombinant plasmid comprising a plasmic vector and the patented claims are directed to a process for producing lactoferrin comprising steps such as transforming an *Aspergillus* cell (i.e., *oryzae*, *niger*, *nidulans* and *awamori*) with an expression vector. The two sets of claims differ in that the patented claims encompass several method steps not recited in the instant claims, however, the instant claims recite the open language "comprising". Furthermore, the patented claims are not directed specifically to a human lactoferrin, however, the broad recitation of "lactoferrin" in the patented claims encompasses the species claimed in the instant application. Therefore, although the conflicting claims are not identical, they are not patentably distinct from each other as the patented claims and the claims of the instant application are obvious variations of each other.

One of ordinary skill in the art would be motivated to modify the instant claims to recite, for example the species human in the instant claim 24 that is contained in the genus as disclosed in claim 14 of the patent because it clarifies the claim by providing

the specific species. Thus, the instant claims are an obvious variation of the patented claims, therefore *prima facie* obvious.

12. Claims 24 and 65 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 16 of U.S. Patent No. 5,571,691. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application is directed to the present application is directed to a process for producing human lactoferrin, which comprises culturing a transformant eukaryotic cell containing a recombinant plasmid comprising a plasmic vector and the patented claims are directed to a process for producing human lactoferrin which comprises transforming a eukaryotic cell with an expression vector containing a DNA encoding a human lactoferrin.... The process of the instant application also comprise using a plasmic vector having a polydeoxyribonucleotide which codes for a human lactoferrin protein in a suitable nutrient medium and isolating the human lactoferrin. The two sets of claims differ in that the patented claims encompass several method steps not recited in the instant claims, however, the instant claims recite the open language "comprising". Furthermore, the patented claims are directed a specific DNA sequence to code for a human lactoferrin, however, the broad recitation of "polydeoxyribonucleotide which codes for a human lactoferrin protein " in the instant claims encompasses the species claimed in the patent application. Therefore, although the conflicting claims are not identical, they are not patentably

Art Unit: 1656

distinct from each other as the patented claims and the claims of the instant application are obvious variations of each other.

One of ordinary skill in the art would be motivated to modify the instant claims to recite, for example the species SEQ ID NO:1 in the instant claim 24 that is contained in the patented claims because it clarifies the claim by providing the specific species. Thus, the instant claims are an obvious variation of the patented claims, therefore *prima facie* obvious.

This is an obvious-type double patenting rejection.

Conclusion

13. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1656

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MSc
Patent Examiner 
